SECTION 5 – 510(K) SUMMARY K112218

DEC 15 2011

Submitted by:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46581 Phone: (305) 269-6386 Fax: (305) 269-6441
Contact Person:	Suzana Otaño, Project Manager, Regulatory Affairs
Date Prepared:	August 1, 2011
Proprietary Name:	ACE-Fischer® External Fixation System
Common Name:	External Fixation Systems
Classification Name:	Appliance, fixation, nail/blade/plate combination, multiple component (21 CFR § 888.3030), KTT; Smooth or threaded metallic bone fixation fastener (21 CFR § 888.3040), JDW
Predicate Devices:	The devices are substantially equivalent to their currently marketed versions.
Device Description:	This submission covers DePuy Orthopaedics' external fixators and their performance in the MR environment. The ACE-Fischer system is classified as MR Unsafe.
Indications for Use:	Indicated for open and closed long bone fracture fixation to include tensioned wire fixation of periarticular fractures, arthrodesis, limb lengthening, osteotomy, reconstruction, non-unions, pseudoarthrosis, correction of bony or soft tissue defects and deformities.
Technological Characteristics:	The technological characteristics of the devices that are the subject of this submission remain unchanged from the predicate in design, material and performance.
Summary of Substantial Equivalence:	The products that are the subject of this submission are equivalent to the predicates and the design and technological characteristics remain unchanged. Evaluation was done based on ASTM F2052 to determine MR compatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DePuy Orthopaedics, Inc.
% Ms. Suzana Otaño
Senior Regulatory Affairs Specialist
700 Orthopaedics Drive
Warsaw, Indiana 46581-0988

DEC 15 2011

Re: K112218
Trade/Device Name: ACE-Fischer External Fixator
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, JDW
Dated: August 25, 2010
Received: August 26, 2010

Dear Ms. Otaño:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

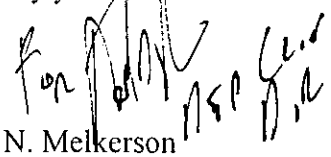
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE STATEMENT

510(k) Number: K112218

Device Name: **ACE-Fischer External Fixation System**

Indications For Use:

Indicated for open and closed long bone fracture fixation to include tensioned wire fixation of periarticular fractures, arthrodesis, limb lengthening, osteotomy, reconstruction, non-unions, pseudoarthrosis, correction of bony or soft tissue defects and deformities.

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR Over-the-Counter _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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